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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,543

06/16/2005

Stefan Berg

100925-1P US

7996

22466

7590

01/28/2008

ASTRA ZENECA PHARMACEUTICALS LP

GLOBAL INTELLECTUAL PROPERTY

1800 CONCORD PIKE

WILMINGTON, DE 19850-5437

EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

01/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,543

Applicant(s)

BERG ET AL.

Examiner

JEFFREY H. MURRAY

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. The compound or composition of the formula I, where Z=N, X=N, and P and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- II. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with at least one nitrogen and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- III. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with at least one nitrogen and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- IV. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with at least one nitrogen and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- V. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with at least one nitrogen and Q is a phenyl ring, according to Claims 1-9.
- VI. The compound or composition of the formula I, where Z=N, X=CH, and P and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- VII. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- VIII. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring with at least one nitrogen and Q

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is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.

- IX. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring with at least one nitrogen and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- X. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring with at least one nitrogen and Q is a phenyl ring, according to Claims 1-9.
- XI. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with only one nitrogen and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XII. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XIII. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XIV. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- XV. The compound or composition of the formula I, where Z=N, X=N, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a phenyl ring, according to Claims 1-9.
- XVI. The compound or composition of the formula I, where Z=N, X=CH, and P is a 6-membered heterocyclic ring with only one nitrogen and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XVII. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XVIII. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.

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- XIX. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- XX. The compound or composition of the formula I, where Z=N, X=CH, P is a 6-membered heterocyclic ring with only one nitrogen and Q is a phenyl ring, according to Claims 1-9.
- XXI. The compound or composition of the formula I, where Z=N, X=N, P is a 5-membered heterocyclic ring with at least one nitrogen and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXII. The compound or composition of the formula I, where Z=N, X=N, P is a 5-membered heterocyclic ring with at least one nitrogen and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XXIII. The compound or composition of the formula I, where Z=N, X=N, P is a 5-membered heterocyclic ring with at least one nitrogen and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXIV. The compound or composition of the formula I, where Z=N, X=N, P is a 5-membered heterocyclic ring with at least one nitrogen and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- XXV. The compound or composition of the formula I, where Z=N, X=N, P is a 5-membered heterocyclic ring with at least one nitrogen and Q is a phenyl ring, according to Claims 1-9.
- XXVI. The compound or composition of the formula I, where Z=N, X=CH, P is a 5-membered heterocyclic ring with at least one nitrogen and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXVII. The compound or composition of the formula I, where Z=N, X=CH, P is a 5-membered heterocyclic ring with at least one nitrogen and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XXVIII. The compound or composition of the formula I, where Z=N, X=CH, P is a 5-membered heterocyclic ring with at least one nitrogen and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXIX. The compound or composition of the formula I, where Z=N, X=CH, P is a 5-membered heterocyclic ring with at least one nitrogen and Q

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- is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- XXX. The compound or composition of the formula I, where Z=N, X=CH, P is a 5-membered heterocyclic ring with at least one nitrogen and Q is a phenyl ring, according to Claims 1-9.
- XXXI. The compound or composition of the formula I, where Z=N, X=N, P is a heterocyclic ring with no nitrogen members and Q is a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXXII. The compound or composition of the formula I, where Z=N, X=N, P is a heterocyclic ring with no nitrogen members and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XXXIII. The compound or composition of the formula I, where Z=N, X=N, P is a heterocyclic ring with no nitrogen members and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXXIV. The compound or composition of the formula I, where Z=N, X=N, P is a heterocyclic ring with no nitrogen members and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- XXXV. The compound or composition of the formula I, where Z=N, X=N, P is a heterocyclic ring with no nitrogen members and Q is a phenyl ring, according to Claims 1-9.
- XXXVI. The compound or composition of the formula I, where Z=N, X=CH, P is a heterocyclic ring with no nitrogen members and Q is a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXXVII. The compound or composition of the formula I, where Z=N, X=CH, P is a heterocyclic ring with no nitrogen members and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XXXVIII. The compound or composition of the formula I, where Z=N, X=CH, P is a heterocyclic ring with no nitrogen members and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XXXIX. The compound or composition of the formula I, where Z=N, X=CH, P is a heterocyclic ring with no nitrogen members and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.

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- XL. The compound or composition of the formula I, where Z=N, X=CH, P is a heterocyclic ring with no nitrogen members and Q is a phenyl ring, according to Claims 1-9.
- XLI. The compound or composition of the formula I, where Z=N, X=N, P is a phenyl ring and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XLII. The compound or composition of the formula I, where Z=N, X=N, P is a phenyl ring and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XLIII. The compound or composition of the formula I, where Z=N, X=N, P is a phenyl ring and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XLIV. The compound or composition of the formula I, where Z=N, X=N, P is a phenyl ring and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- XLV. The compound or composition of the formula I, where Z=N, X=N, P is a phenyl ring and Q is a phenyl ring, according to Claims 1-9.
- XLVI. The compound or composition of the formula I, where Z=N, X=CH, P is a phenyl ring and Q are a 6-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XLVII. The compound or composition of the formula I, where Z=N, X=CH, P is a phenyl ring and Q is a 6-membered heterocyclic ring with only one nitrogen, according to Claims 1-9.
- XLVIII. The compound or composition of the formula I, where Z=N, X=CH, P is a phenyl ring and Q is a 5-membered heterocyclic ring with at least one nitrogen, according to Claims 1-9.
- XLIX. The compound or composition of the formula I, where Z=N, X=CH, P is a phenyl ring and Q is a heterocyclic ring with no nitrogen members, according to Claims 1-9.
- L. The compound or composition of the formula I, where Z=N, X=CH, P is a phenyl ring and Q is a phenyl ring, according to Claims 1-9.
- LI. The compound or composition of a compound or composition not previously described in the above groups, according to Claims 1-9.
- LII. The use of a compound of any one of the above groups, according to Claim 10.
- CIII. The use of a compound of any one of the above groups, according to Claims 11-12.
- CLIII. The use of a compound of any one of the above groups, according to Claims 11-12.

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CLIV-	The use of a compound of any one of the above groups, according
CCIV.	to Claim 14.
CCV-	A method of prevention and/or treatment using a compound of one
CCLV.	of the above groups, according to Claim 15.
CCLVI-	A method of prevention and/or treatment using a compound of one
CCCVI.	of the above groups, according to Claims 16-17.
CCCVII-	A method of prevention and/or treatment using a compound of one
CCCLVII.	of the above groups, according to Claim 18.
CCCLVIII-	A method of prevention and/or treatment using a compound of one
CDVIII	of the above groups, according to Claim 19.
CDIX-	The use of the intermediate, according to Claim 20.
CDLX.	
CDLX-	The use of a compound of any one of the above groups, according
CDCX.	to Claim 13.

2. The inventions listed as Groups I - CDCX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the claims is a compound of general formula I. Groups I-LI are directed to structurally dissimilar compounds or compositions such that the variable core created by varying the definitions of the formula do not belong to a recognized class of chemical compounds in the art, and references anticipating one invention would not render obvious the others. For example, the compound of: 3-amino-6-phenyl-N-(pyrimidin-5-yl)pyrazine-2-carboxamide is not the same as the compound of a 1-(2-amino-5-(pyrimidin-4-yl)pyridin-3-yl)-3-(1H-imidazol-5-yl)urea. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could

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support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structures as functional equivalents of each other. The mere fact that there is a single similarity is not in itself a significant reason to render the whole embodiment obvious. Therefore, the feature linking the claims does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art.

Accordingly, Groups I – CDCX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. This application contains claims directed to the following patentably distinct species: all the defined diseases of Claims 11-14 and 16-19. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 and 43 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Examiner, Art Unit 1624

James O. Wilson
Supervisory Patent Examiner
Art Unit 1624